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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,042	05/15/1998	SUN-YOUNG KIM	003364.P001	5584

7590 03/10/2003

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EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,042

Applicant(s)

KIM ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,9-11,13-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,9,10,13-15 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 5,11,13,14,18 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 15 February 2002 (Paper No. 31) has been entered in full. Claims 2, 6, 8, 12 and 16 were cancelled. Claims 1, 3-7, 9-11, 13-15, 17-21 are under examination.

Korean Patent Application No. 1995-0026391 and the certified translation of the document have been entered (15 February 2002, Paper No. 30), however the priority date of the instant application is still 23 August 1996 because the declaration of the instant application makes no claim to Korean Patent Application No. 1995-0026391.

The amendment filed 16 July 2002 (Paper No. 36) has been entered in full.

The amendment filed 20 November 2002 (Paper No. 38) has been entered in full.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection of claims 2, 5, 6, 8, 11-14, 16, 19, 21 as set forth at page 4 of the previous Office Action (03 October 2001, Paper No. 28) is *withdrawn* in view of the amendment (15 February 2002, Paper No. 31).

The rejection of claim 19 under 35 U.S.C. 112, second paragraph as set forth at pages 4-5 of the previous Office Action (03 October 2001, Paper No. 28) is *withdrawn* in view of the amendment (15 February 2002, Paper No. 31).

The rejection of claims 1, 7, 15 and 20 under 35 U.S.C. 102(e) as being anticipated by Donson *et al.* U.S. Patent No. 6,284,492 as set forth at pages 5-6 of the

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previous Office Action (03 October 2001, Paper No. 28) is *withdrawn* in view of the amendment (15 February 2002, Paper No. 31).

The rejection of claim 20 under 35 U.S.C. 102(e) as being anticipated by Borden *et al.* U.S. Patent No. 5,968,823 as set forth at page 6 of the previous Office Action (03 October 2001, Paper No. 28) is *withdrawn* in view of the amendment (15 February 2002, Paper No. 31).

The rejection of claims 1, 7, 15, 20 and 21 under 35 U.S.C. 102(b) as being anticipated by Bosselman *et al.* U.S. Patent No. 5,162,215 as set forth at pages 6-7 of the previous Office Action (03 October 2001, Paper No. 28) is *withdrawn* in view of the amendment (15 February 2002, Paper No. 31).

The rejection of claims 2, 8 and 16 under 35 U.S.C. 103(a) as being unpatentable over Bosselman *et al.* U.S. Patent No. 5,162,215 in view of Borden *et al.* U.S. Patent No. 5,968,823 as set forth at page 8 of the previous Office Action (03 October 2001, Paper No. 28) is *withdrawn* in view of the amendment (15 February 2002, Paper No. 31).

Sequence Rules

The instant application fails to fully comply with the sequence rules 37 CFR 1.821-1.825 because there is a discrepancy between the SEQ ID Nos in the figures and the SEQ ID Nos in the paper copy of the sequence listing.

SEQ ID NO:1 (AM) is recited as having 1585 nucleotides in the paper copy, but has 1584 nucleotides in Figure 5H.

SEQ ID NO:2 (GI) is recited as having 1583 nucleotides in the paper copy, but has 1582 nucleotides in Figure 5H.

SEQ ID NO:4 (JM) is recited as having 1586 nucleotides in the paper copy, but has 1585 nucleotides in Figure 5H.

SEQ ID NO:6 (HE) is recited as having 1587 nucleotides in the paper copy, but has 1586 nucleotides in Figure 5H.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. SH was isolated from a person, thus it is a naturally occurring protein and reads on products of nature (specification, page 14, lines 10-11; page 16, lines 3-18).

Claim Rejections - 35 USC § 102(e)

Claims 1, 4, 7, 10, 15, 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Cochran *et al.*, U.S. Patent No. 5,965,138. The claims are generally drawn to an EPO production system comprising a DNA encoding EPO, a vector comprising HCMV MIEP for receiving DNA, an avian cell for harboring the vector and a method of producing the protein.

Cochran teaches vectors for producing a recombinant herpesvirus of turkeys, host cells, and methods (abstract). Cochran teaches the use of herpesvirus of turkeys (HVT) as a viral vector (column 1, lines 63-66 and column 5, lines 14-16). Foreign DNA sequences are inserted into non-essential sites in the HVT genome and its expression is under the control of a promoter located upstream of the foreign DNA sequence (column 8, lines 14-20). Cochran teaches foreign DNA or gene to mean any DNA or gene that is exogenous to the genomic DNA (column 8, lines 25-29). Thus Cochran teaches expressing genomic DNA. Cochran teaches that the foreign DNA sequence is under control of a heterologous upstream promoter including the HCMV immediate early promoter (column 14, lines 51-58 and claims). It is noted that HCMV "immediate early" and HCMV "major immediate early" are used interchangeably in the art. Please see the review on human cytomegalovirus (Castillo *et al.*, Gene 290:19-34, 2002). Cochran teaches that the invention provides a host cell infected with the recombinant herpesvirus of turkey where the host cell is an avian cell. The host cell is used to propagate the vector and its insert (column 17, lines 3-8). Cochran teaches methods for constructing, selecting and purifying recombinant herpesvirus of turkeys (column 17, lines 16-62). Cochran teaches that the cytokine erythropoietin can be expressed in recombinant HVT. Cochran teaches that these cytokines can be from humans (column 63, lines 17-46). Thus Cochran teaches a human heterologous system.

Claim Rejections - 35 USC § 112, First paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 9, 17 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention appears to employ novel avian cells (i.e., cell line QT-VC). Since the cells are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the cells are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the cell line. The specification does not disclose a repeatable process to obtain the cell line and it is not apparent if the cell line is readily available to the public. It is noted that Applicant has deposited the cell line (p. 3, lines 8-12 of the specification), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the nucleic acid molecules will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an

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affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Claim Rejections - 35 USC § 112, Second paragraph

Claims 15 and 17 (dependent claim) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites, "an avian cell as a host for expressing EPO controlling an HCMV MIEP promoter". It is unclear if the claimed avian cell actually comprises EPO or HCMV MIEP sequences or if merely has to be a host cell. The metes and bounds of the claim cannot be determined.

Claim Objections

Claims 5, 11, 13, 14, 18 and 20 are objected to because of the following informalities:

Claims 5, 11 are objected to because they depend from a rejected claim.

Claims 13 and 14 are objected to because of the language "selected from the group consisting of SH". It is suggested to use the word "comprising".

Claims 18 and 20 are objected to because they are not limited to the elected invention. Appropriate correction is required.

Conclusion

Claims 1, 3, 4, 7, 9, 10, 13-15, 17-21 are rejected.

Claims 5, 11, 13, 14, 18, 20 are objected to.

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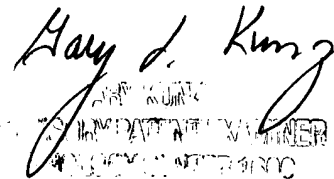
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
March 7, 2003


TO THE INVENTOR
BY: GARY L. KUNZ
REGISTERED PATENT ATTORNEY